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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
STILLER, KARL J

ART UNIT	PAPER NUMBER
1617	4

DATE MAILED: 12/18/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/921,947	Applicant(s) CREPEAU, MICHAEL ANDRE	
	Examiner Karl Stiller	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising the precursor of vitamin A, retinyl propionate with or without vitamin D3, and/or the precursor of vitamin E, dl alpha tocopherol acetate with or without vitamin D3 (see specification, p. 3, lines 16-21, p. 7-8, Table 1, especially "**Precursor**", p. 10-14, Examples 1-5), does not reasonably provide enablement for any 2 or more precursors of vitamin A with or without vitamin D3, and/or any 2 or more precursors or vitamin E with or without vitamin D3. The specification does not reasonably enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

1. **Nature of the invention:** The instant invention pertains to a composition comprising one or more precursors of vitamin A and/or one or more precursors of vitamin E and/or vitamin D3, a C4-C6 alkyl lactate, one or more veterinarily acceptable emulsifiers, water, and oil.
2. **The state of the prior art:** The skilled artisan would view vitamins to be a diverse group of compounds which encompass numerous organic chemicals, the

precursors of which may constitute carbon, any of a number of pro-vitamins which are metabolized *in vivo* to the vitamin, and all intervening compounds.

3. **The predictability or lack thereof in the art:** It is a well-settled fact that metabolism of pro-drugs or pro-vitamins are often not predictable. It is well known that enzyme systems to metabolize pro-drugs or pro-vitamins differ between animal species, and that efficacy or toxicity often cannot be accurately predicted for one species, given the administration of the compound to another. It is also well known that a single atom addition or omission to any compound often results in the compound having an unpredictable biological activity. Because a compound necessarily needs the metabolic conversion from the pro-drug or pro-vitamin to the drug or vitamin in order to be considered a precursor thereof, and since the metabolism of any compound is unpredictable between species, undue experimentation would be required in order to further identify "precursors" of vitamins A and E useful in the compositions herein.
4. **The amount of direction or guidance present:** The specification provides one example of a vitamin A precursor, one example of a vitamin E precursor, and the speculative inclusion of optionally substituted oily derivatives of the vitamins (see specification, p. 3, lines 16-21, p. 7-8, Table 1, especially "**Precursor**", p. 10-14, Examples 1-5).
5. **The presence or absence of working examples:** Seventeen examples of compositions employing the vitamin A precursor, retinyl propionate, alone, as a

vitamin precursor are given (see p. 9, line 1 through p. 11, line 11). A single example of a composition employing the vitamin E precursor, dl alpha tocopherol acetate, alone, as a vitamin precursor is given (see p. 11, line 14 through p. 12, line 14). A single example of a composition employing vitamin D3, alone, is given (see p. 12, line 15 through p. 13, line 11). A single example of a composition employing the vitamin A precursor, retynyl propionate, the vitamin E precursor, dl alpha tocopherol, and vitamin D3 is given (see p. 13, line 15 through p. 14, line 15).

Therefore, since the art of metabolic conversion is highly unpredictable, little direction and guidance was provided in the specification, and very limited examples of what may be considered precursors to vitamins A and E, undue experimentation would be required to practice the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 13, 24, 42, and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "adequately" in Claim 13 is a relative term which renders the claim indefinite. The term "adequately" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear as to

the degree of dispersion of the composition into water necessary in order to be considered "adequate".

The term "substantially" in Claims 5, 24, 42, and 43 is a relative term which renders the claims indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear as to how much of a flammable alcohol (Claim 5) or a mono-hydroxy alcohol (Claim 24) the composition herein may contain and still be considered "substantially" free of the alcohol. It is unclear as to what degree the composition herein may be flammable (Claims 42 and 43) and still be considered "substantially" non-combustible.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over M.V.I.-12 ® package insert (11-2000) in view of Multi-12 ® package insert (5-2000), The Merck Index (1989), and Lundberg (1999).

M.V.I.-12 package insert discloses a water-dispersible, substantially non-combustible and substantially flammable-alcohol/mono-hydroxy alcohol free liquid

vitamin composition comprising the vitamin A precursor oil, retinol, the vitamin E precursor oil, dl-alpha tocopheryl acetate, vitamin D2 oil. The veterinarily acceptable emulsifier/non-ionic surfactant/solubilizer, polysorbate 80, water, the veterinarily acceptable stabilizer, propylene glycol, the antioxidants, BHT and BHA, and the antifungal preservative, gentisic acid ethanolamide (see column 1, "DESCRIPTION", ""Aqueous" multivitamin formula for intravenous infusion", column 2, "DESCRIPTION", ""Aqueous" multivitamin formula for intravenous infusion").

The reference does not particularly disclose the employment of vitamin D3 oil, a C4 to C6 alkyl lactate solubilizer or the antioxidant, ethoxyquin. The reference also does not particularly disclose the percentage ranges of weights and ratios of actives and excipients useful herein, the flashpoint temperature, the water dispersion time, or the viscosity of the compositions.

Multi-12 ® package insert discloses a water-dispersible, substantially non-combustible and substantially flammable-alcohol/mono-hydroxy alcohol free liquid vitamin composition comprising the vitamin A precursor oil, vitamin A palmitate, the vitamin E precursor oil, dl-alpha tocopheryl acetate, vitamin D3 oil, the veterinarily acceptable emulsifier/non-ionic surfactant/solubilizer, polysorbate 80, and water (see p. 1, DESCRITION, p. 7, DRAFT INNER LABEL, p. 9, DRAFT OUTER LABEL (*BACK PANEL*), p. 10, DRAFT OUTER LABEL (*BACK PANEL*)).

The Merck Index discloses that ethoxyquin is a known antioxidant used in food (see p. 593, item 3710).

Lundberg discloses that sec-butyl lactate, isobutyl lactate, and n-butyl lactate are known solvents for oils and are useful as food additives (see p. 3, lines 1-25, p. 4, lines 33-37).

It would have been obvious to modify the M.V.I.-12 ® reference by employing vitamin D3 oil. It would also have been obvious to modify the M.V.I.-12 ® reference by employing a C4 to C6 alkyl lactate solubilizer and the antioxidant, ethoxyquin.

One of ordinary skill would have been motivated to employ vitamin D3 oil in the M.V.I.-12 ® composition since its employment and compatibility in a similar aqueous multivitamin composition is clearly demonstrated in the Multi-12 ® package insert. One of ordinary skill would also have been motivated to employ a C4 to C6 alkyl lactate solubilizer in place of or in addition to the polysorbate 80 solubilizer since it is considered *prima facie* obvious to substitute any known solubilizer with another known solubilizer in the composition, absent evidence to the contrary. Similarly, one of ordinary skill would have been motivated to employ the antioxidant, ethoxyquin, in the disclosed composition since it is considered *prima facie* obvious to substitute any known antioxidant, such as BHT or BHA, with another known antioxidant, absent evidence to the contrary.

Further, one of ordinary skill would have been motivated to employ the percentage ranges of weights and ratios of actives and excipients useful herein to obtain the recited flashpoint temperature, water dispersion time, and composition viscosity since the optimization of a value of a result effective variable in a known

process is considered within the skill of the artisan as optimization of a result effective parameter. See *In re Boesch* 205 USPQ 215.

Thus, Claims 1-6 fail to patentably distinguish over the state of the art as represented by the cited references.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karl Stiller whose telephone number is 703-306-3219. The examiner can normally be reached Monday through Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached at 703-308-4612. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4556 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Stiller: ks
December 14, 2001

MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
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